MC 4-262 6720 Bertner Avenue Houston, TX 77030 P 832,355.1000 CHIStLukesBaylon.org

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February 25, 2019

# ORIGINAL PLAN OF CORRECTION AND ATTACHMENTS BY OVERNIGHT DELIVERY AND VIA EMAIL

Department of Health & Human Services
Centers for Medicare & Medicaid Services
Dallas Regional Office
Attn: Karen Hillman, Manager – Enforcement Branch
1301 Young Street, Room 827
Dallas, Texas 75202

Texas Health and Human Services Commission Jennifer Berger, Manager Jennifer.Berger@hhsc.state.tx.us

Re: CHI St. Luke's Health Baylor College of Medicine Medical Center ("Baylor St. Luke's Medical Center") Reference No. CCN 450193 Intake #TX00303301

Dear Ms. Hillman and Ms. Berger:

I am the President of Baylor St. Luke's Medical Center in Houston, Texas. As you know, from January 7, 2019 to January 11, 2019, the Centers for Medicare & Medicaid Services ("CMS"), in conjunction with the Texas Health and Human Services ("THHSC") surveyed Baylor St. Luke's Medical Center based on complaint intake number 181344022. As a result of alleged deficiencies discovered during that survey, CMS provided a 2567 Statement of Deficiencies alleging noncompliance with certain CMS Hospital Conditions of Participation and removing Baylor St. Luke's Medical Center's "deemed status" as of February 7, 2019.

Though a Plan of Correction ("POC") is not required, Baylor St. Luke's Medical Center is submitting one to demonstrate to CMS and HHSC how seriously Baylor St. Luke's Medical Center is taking this matter. Based on documentation contained in the enclosed Plan of Correction ("POC"), Baylor St. Luke's Medical Center believes that it complies with the cited Hospital Conditions of Participation. Accordingly, Baylor St. Luke's Medical Center requests that you accept the POC as credible evidence of correction and that you reinstate Baylor St. Luke's Medical Center's deemed status.

## **Baylor St. Luke's Medical Center Corrective Action**

Baylor St. Luke's Medical Center has taken swift and decisive actions in order to ensure compliance with Hospital Conditions of Participation and to address the CMS-2567

Statement of Deficiencies (the "2567"). Immediately after the survey and prior to receiving the CMS 2567, Baylor St. Luke's Medical Center took action to begin addressing those concerns expressed by the surveyors in the exit conference. Those efforts included review of and revisions to relevant policies, review of documentation processes in all affected areas of the hospital, internal review of the patient charts discussed with the surveyors, implementation of an audit process, and educational sessions for physicians and staff. As you can see, there are specific dates for each action summarized on the POC, and the latest date for correction of any part of any deficiency is March 6, 2019.

# Baylor St. Luke's Medical Center Services to the Community

Baylor St. Luke's Medical Center is licensed for 879 acute beds, including 30 acute inpatient rehabilitation beds. In FY 2018 Baylor St. Luke's Medical Center admitted 23,334 patients, and outpatient visits totaled 115,901, excluding emergency visits. Baylor St. Luke's Medical Center provides full range of services including Anesthesia Service, Cardiac Catheterization Laboratory, Cardiac-Thoracic Surgery, Chemotherapy Services, CT Scanner, Dietetic Service, Emergency Department (Dedicated), ICU - Cardiac (non-surgical), ICU - Medical/Surgical, ICU - Surgical, Laboratory-Clinical, Magnetic Resonance Imagining (MRI), Neurosurgical Services, Nuclear Medicine Services, Occupational Therapy Services, Operating Rooms, Ophthalmic Surgery, Orthopedic Surgery, Outpatient Services, Pharmacy, Physical Therapy Services, Positron Emission Tomography Scan, Post-Operative Recovery Rooms, Radiology Services – Diagnostic, Radiology Services – Therapeutic, Reconstructive Surgery, Respiratory Care Services, Rehab Services – Inpatient, Rehab -Outpatient, Renal Dialysis (Acute Inpatient), Social Services, Speech Pathology Services, Surgical Services – Inpatient, Surgical Services – Outpatient, and Transplant Center (Medicare Certified).

Baylor St. Luke's Medical Center, while not a Trauma Center, has a very busy Emergency Department. In FY 2018, Emergency Department visits totaled 61,455.

Baylor St. Luke's Medical Center and its Medical Staff members and personnel provide numerous resources to the Greater Houston community. Baylor St. Luke's Medical Center is also a significant employer within the community. Baylor St. Luke's Medical Center is also committed to providing care to all patients regardless of economic status. In FY 2018, Baylor St. Luke's Medical Center provided \$20.1 million (at cost) in charity care to the community.

During the prior fiscal year, Baylor St. Luke's Medical Center inpatients demonstrated the following payor mix: 49.3% Medicare, 6.8% Medicaid, 0.2% Commercial, 38.4% managed care and 5.2% self pay and other.

As this information demonstrates, Baylor St. Luke's Medical Center's service area relies heavily on the Hospital to provide crucial "safety net" services to individuals who may otherwise go without care as well as a number of valuable services to the community as a whole.

### Conclusion

Baylor St. Luke's Medical Center is a valuable and unique asset to the community it serves. Baylor St. Luke's Medical Center provides much needed and readily available patient

care services. Baylor St. Luke's Medical Center believes that it is in compliance at this time with CMS Hospital Conditions of Participation and has taken prompt and comprehensive actions to ensure that it remains in compliance. Based on the actions described above, along with the detailed responses described in the POC, Baylor St. Luke's Medical Center respectfully requests that CMS reinstate Baylor St. Luke's Medical Center's deemed status.

If you have any questions or require additional supporting documentation with regard to Baylor St. Luke's Medical Center compliance with applicable Hospital Conditions of Participation or any other related matter, please do not hesitate to contact me. You may also contact Megan Fischer, Vice President of Quality at <a href="mailto:mfischer3@stlukeshealth.org">mfischer3@stlukeshealth.org</a> or 832-355-8996.

Very truly yours,

T. Douglas Lawson, PhD

President

cc:

Mr. Dodjie Guioa, CMS

Ms. Megan Fischer, Baylor St. Luke's Medical Center

Enclosed:

Plan of Correction

### DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 02/05/2019 FORM APPROVED OMB NO. 0938-0391

	STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	1 ` ′	MULTIPLE CONSTRUCTION UILDING		OATE SURVEY OMPLETED
MANE OF PROVIDER ON SUPPLIER  CHI ST LUKE'S HEALTH BAYLOR COLLEGE OF MEDICINE ME  SIMMARY STATEMENT OF DEFICIENCIES (EACH OFFICIENCIES MEDICINE MED			450193	B. WING_	B. WING		
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FORM CMS-2567(02-99) Previous Versions Obsolete

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued

# Centers for Medicare and Medicaid Services (CMS) Conditions of Participation (CoP) **Provider Plan of Correction**

Provider Name	rovider Name CHI St Luke's Health Baylor College of Medicine Medical Center	Provider Identification # 450193	450193	Date of Survey	1/11/2019
Address	6720 Bertner Avenue Houston, TX 77030	Complaint Intake #	TX00303301 TX181344022	Survey Type	CMS

Participation) under Tags A115, A263, A385. BSLMC has corrected all cited deficiencies and has taken steps for sustained compliance with the CoPs over time to ensure safe, quality care for patients. Accordingly, BSLMC respectfully requests that CMS (Centers for Medicare and Medicaid) accept this Plan of Correction Tag A 000 - Through a collaborative effort of Baylor St. Luke's Medical Center's (BSLMC or "Hospital") Senior Leadership, administration, the laboratory, nursing staff, the medical staff and the Governing Body, BSLMC has taken prompt and significant corrective actions to ensure compliance with the CoPs (Conditions of (PoC) as credible evidence of current and long-term sustained compliance with the CoPs. BSLMC is currently in compliance with the CMS Condition of Participation A115 as evidence by the following specific corrective actions, education and monitoring for compliance.

**Completion Date** Completion Date: Responsible **Nursing Officer** Person: Chief Person Responsible 3/5/2019 Leadership Team audits 20 randomly specimens per week with a monthly chaired by the President or Senior Leader selected Transfusion Services blood member of the Transfusion Service misidentification (wrong blood in monitoring measures. This council will measures until 100% compliance with designee will meet weekly to provide oversight of the compliance with the continue to oversee the monitoring aggregate of 80 to validate the Through direct observation, a An Executive Quality Council (EQC), stated measures is sustained for 3 process of correctly rejecting Monitoring Compliance mislabeled specimens and months. member of the Transfusion Services Leadership on specimens that are not properly labeled with The Transfusion Services Staff were educated by a the electronic record's specimen label or the ABO Rh must be confirmed on two separate label from an electronic down time process. Transfusion Services will not accept blood specimens which contain more than one accordance with the hospital's policy for Transfusion Services will not accept any the revised policy to reinforce the following: reinforced the following pre-existing policy The Transfusion Services staff education Report all mislabeled specimens in Education specimens. statements: label. ن 0 specimen collection is in response to a process. This was conveyed with staff prior to drawing blood and adherence ED Leadership clarified to the nursing patient identifier verification process. staff the only acceptable practice for transfusion reaction criteria and the to the patient identifier verification Nursing Leadership reviewed policy involved in the event and managed The Transfusion of Blood Productsphysician order and the use of the requirement for a physician order Patient Care Policy was revised to include: revisions to the blood through the Human Resources expectations regarding the **Corrective Actions** corrective action process. CoP Tag A115

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

requirement for ABO Rh on two separate specimens be confirmed before the Transfusion Services will issue non-group O blood.

- The Specimen Identification, Collection Labeling and Transportation Pathology policy was revised to delineate the use of the patient identifier verification process and the required process for labeling specimens at the bedside.
- The Specimen Identification, Collection Labeling and Transportation Pathology policy was revised to clarify the process for rejecting specimens that do not have electronic record's specimen label required for processing. This includes rejection of double labels, misidentification (wrong blood in tube) and defines the unacceptable labeling practices that will require the specimen to be rejected.
- In the event of specimen rejection, the Transfusion Services Team Member notifies the departmental leader for follow up as to the reason for deviation from following policy. Appropriate action may include: reeducation, training and/or following the Human Resources corrective action process.
- The Environmental Services (EVS) standard work plan was modified to include the process for notification to ED staff if bodily fluids are left in the room of a discharged patient. EVS will not begin the cleaning process of any room until all bodily fluids and specimens are removed from the

specimen labeling.

Transfusion Services Staff presently on FMLA or LOA will complete the education prior to returning to work.

- Nursing Leadership conducted educational training for nursing staff that took place across all shifts and is reinforced by regular nursing leadership rounding to assess competencies.

  Training has taken place for permanent full time and part time nurses and contract nurses.

  Education reflected the hospital policies and included:
- Specimens can only be drawn with an order and not left in a patient room.
- o Drawing specimens and labeling containers using the patient identifier verification process.
- O Documentation of vital signs, Temperature,
  Heart Rate, Respiratory Rate, 5pO2, Blood
  Pressure and use of supplemental oxygen
  prior to, during, and after blood
  administration.
- Frequency of vital sign monitoring during blood administration.
- Monitoring of patients receiving blood transfusions, including the replacement of the EMR alert.
- o Identification of possible signs and symptoms of blood transfusion reactions, processes to stop the transfusion and immediate notification to the Transfusion Services.
- Reporting quality and safety concerns.

Nursing staff on FMLA or LOA will complete the training prior returning to work.

Specimen labeling, blood administration, and blood transfusion reactions are included in

tube) in accordance with the policy. The findings are reported monthly to the Transfusion Committee, Quality of Care Committee, Medical Executive Committee and quarterly to the Quality Committee of the Board of Trustees until 100% is sustained for 3 months.

- Through direct observation, a member of the EVS Leadership team audits 10 rooms cleaned by EVS staff members per week with a monthly aggregate of 40 to validate the new process regarding EVS not cleaning a room until all specimens are removed is in place. The findings are reported monthly to the Transfusion Committee, Quality of Care Committee, Medical Executive Committee and quarterly to the Quality Committee of the Board of Trustees until 100% is sustained for 3 months.
- Through direct observation, a member of the ED Leadership team audits 10 instances of specimen collection by ED staff members per week with a monthly aggregate of 40 to validate the specimen collection policy is followed. The findings are reported monthly to the Transfusion Committee, Medical Executive Committee and quarterly to the Quality Committee of the Board of Trustees until 100% is sustained for 3 months.
- Fifty (50) blood transfusion administration records are audited per week with a monthly aggregate

room by ED staff.	
A retrospective audit of 500 charts was conducted to evaluate current	

- compliance with the Transfusion of **Blood Products-Patient Care Policy** and the identification of possible olood transfusion reactions. A ret was
- nursing new staff orientation and incorporated into the competency assessment of blood transfusions.
- LOA will complete the training prior to returning is reinforced by regular EVS leadership rounding for EVS staff that took place across all shifts and from the room by the ED Staff before beginning to clean a room. EVS staff presently on FMLA or EVS Leadership conducted educational training to assess all bodily fluids have been removed to work.
- reactions through one or more of these methods Residents were notified of the policy changes for provided education related to blood transfusion the nursing and laboratory teams. They were online module, discussion at medical staff meetings, and grand rounds.
- blood transfusion reactions through one or more teams. They were provided education related to policy changes for the nursing and laboratory Credentialed Providers were notified of the of these methods in-person training, and discussion at medical staff meetings.

- findings are reported monthly to the accordance with hospital policy. The Care Committee, Medical Executive Trustees until 100% is sustained for Transfusion Committee, Quality of Quality Committee of the Board of Committee and quarterly to the of 200 by nursing leadership for administration of blood in 3 months.
- reaction in accordance with hospital identification of a blood transfusion per week with a monthly aggregate Irustees until 100% is sustained for administration records are audited Quality Committee of the Board of policy. The findings are reported of 200 by nursing leadership for Committee and quarterly to the Committee, Medical Executive Committee, Quality of Care Fifty (50) blood transfusion monthly to the Transfusion 3 months.
- reported monthly to the Transfusion and analyzed by a Pathologist daily. transfusion reactions are reviewed Results are aggregated monthly by Quality Committee of the Board of Committee and quarterly to the Committee, Medical Executive Committee. The findings are the Transfusion Services and reported to the Transfusion Committee, Quality of Care All reported possible blood Irustees.

Individual deficiencies will be reported to manager. Any deficiencies will be the appropriate supervisor or

addressed with the individual through training, re-education and/or following the human resources corrective action process.	When 100% compliance is sustained for 3 months the monitoring will continue on an ongoing basis quarterly. If compliance is not sustained quarterly monitoring will go back to weekly with data aggregated monthly for sustained compliance for at least 3 consecutive months. Decisions will be made in accordance with national	clinical standards and regulations.

BSLMC is currently in compliance with the CMS Condition of Participation A263 as evidence by the following specific corrective actions, education and monitoring for compliance.

**Completion Date** Completion Date: Responsible Person: Vice Person Responsible President of 3/6/2019 Quality Leader designee will meet weekly to Committee of the Board of Trustees. provide oversight of the compliance with the monitoring measures. This **Executive Committee and the Board** council will continue to oversee the compliance with stated measures is reported quarterly to the Quality of Care Committee, Medical Executive The meeting minutes of the Quality An Executive Quality Council (EQC), chaired by the President or Senior monitoring measures until 100% of Trustees show approval of the Safety and quality concerns are analyzed and corrective actions Committee and to the Quality developed. The findings are Monitoring Compliance of Care Committee, Medical sustained for 3 months. Hospital Management Team on the tiered huddle safety and quality concerns in multiple venues to reinforce the expectation to identify and report The revised Quality Assurance and Performance Nursing staff and phlebotomists participated in The Performance Excellence Team trained the approach which was then implemented at the assess competencies. Training has taken place improvement plan was calendared for review Medical Executive Committee and the Quality training that took place across all shifts and is orientation, discussion in hospital committee reinforced by regular leadership rounding to Education was developed and distributed to and approval on Quality of Care Committee, include in person training, new employee Committee of the Board of Trustees. meetings, and leadership rounding. Education unit/department level. Program by reporting to the Hospital's The hospital's Transfusion Committee policy. This Committee is responsible Charter has been updated to include administration and blood transfusion for the analysis of trends and quality transfusion process. The Committee measures the committee monitors. A new position was created, Nurse reactions for compliance with the collaborates with the Manager of This Committee is responsible to Senior Leadership and identifies Hospital's Quality Improvement Management, to improve blood transfusion safety. This position has been incorporated into the Practitioner for Patient Blood improvements of the blood Quality of Care Committee. monitor blood transfusion **Corrective Actions** CoP Tag A263

updated to include blood transfusion	e de la companya de		
 administration and documentation,			
 blood transfusion reactions, specimen			
 collection and labeling.		3	
 utilen of actorial transmit			
me callent bill ector of daily			
position has been expanded to vice			
 President of Quality. This position is a			
member of the Senior Leadership			
Team and is responsible for oversight			
and implementation of the QAPI			
program. The position was hired into			
on 1/14/2019.			
<ul> <li>Bar code label printer functionality</li> </ul>			
verification was completed and			
identified printers not working were			
 repaired or replaced. Further			
identified printer issues are			
incorporated in the Hospital's tiered			
huddle approach.			

BSLMC is currently in compliance with the CMS Condition of Participation A385 as evidence by the following specific corrective actions, education and monitoring for compliance.

		Education	Monitoring Compliance	Person
				Responsible Completion Date
Nursing Leadership reviewed policy	olicy •	Education on specimen labeling and rejection of	An Executive Quality Council (EQC),	Responsible
expectations regarding the		improperly labeled specimens was added to new	chaired by the President or Senior Leader	Person: Chief
requirement for a physician order		employee orientation for all Transfusion Services	designee will meet weekly to provide	Nursing Officer
prior to drawing blood and		Staff.	oversight of the compliance with the	
adherence to the patient identifier		The second secon	monitoring measures. This council will	Completion Date:
verification process. This was	•	rational production of the concentration of the con	continue to oversee the monitoring	3/5/2019
conveyed with staff involved in the		training for nursing staff that took place across an	measures until 100% compliance with	
event and managed through the		Some said is reminisced by regular mushing	stated measures is sustained for 3	
Human Resources corrective action		reduction of the competencies.	months.	
		Iraining has taken place for permanent full time		
		and part time nurses and contract nurses.	Theory of the chick the contract of the contract of the chick of the c	
ED Leadership clarified to the nursing		Education reflected the hospital policies and	- Illiough unect observation, a	
staff the only acceptable practice for		included:	todachia Toom andia 20 tandomia	
specimen collection is in response to			Leauership team addits zo ramonny	
a physician order and the use of the		o specimens can only be drawn with an order	selected Transfusion Services blood	

patient identifier verification process.

- The Specimen Identification,
  Collection Labeling and
  Transportation Pathology policy
  was revised to delineate the use of
  the patient identifier verification
  process and the required process for
  labeling specimens at the bedside.
- The Specimen Identification,
  Collection Labeling and
  Transportation Pathology policy
  was revised to clarify the process for
  rejecting specimens that do not have
  electronic record's specimen label
  required for processing. This includes
  rejection of double labels,
  misidentification (wrong blood in
  tube) and defines the unacceptable
  labeling practices that will require
  the specimen to be rejected.
- In the event of specimen rejection, the Transfusion Services Team Member notifies the departmental leader for follow up as to the reason for deviation from following policy. Appropriate action may include: reeducation, training and/or following the Human Resources corrective action process.
- The Transfusion of Blood Products-Patient Care Policy was revised to include: revisions to the blood transfusion reaction criteria and the requirement for ABO Rh on two separate specimens are confirmed before the Transfusion Services will issue non-group O blood.

and not left in a patient room.

Drawing specimens and labeling containers using patient identifier process.

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- o Documentation of vital signs, Temperature,
  Heart Rate, Respiratory Rate, SpO2, Blood
  Pressure and use of supplemental oxygen
  prior to, during, and after blood
  administration.
- Frequency of vital sign monitoring during blood administration.
- Monitoring of patients receiving blood transfusions.

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- Transportation of blood products.
- o Identification of possible signs and symptoms of blood transfusion reactions, processes to stop the transfusion and immediate notification to the Transfusion Services.
- "Accept and Complete" reminder to complete the transfusion administration documentation in the EMR.
- Monitoring of patients receiving blood transfusions, including the replacement of the EMR alert.
- Reporting quality and safety concerns.

Nursing staff on FMLA or LOA will complete the training prior returning to work.

- Specimen labeling, blood administration, and blood transfusion reactions are included in nursing new staff orientation and incorporated into the competency assessment of blood transfusions.
- EVS Leadership conducted educational training for EVS staff that took place across all shifts and is reinforced by regular EVS leadership rounding to assess all bodily fluids have been removed

specimens per week with a monthly aggregate of 80 to validate the process of correctly rejecting mislabeled specimens and mislabeled specimens and misidentification (wrong blood in tube) in accordance with the policy. The findings are reported monthly to the Transfusion Committee, Quality of Care Committee, Medical Executive Committee and quarterly to the Quality Committee of the Board of Trustees until 100% is sustained for 3 months.

- Through direct observation, a member of the EVS Leadership team audits 10 rooms cleaned by EVS staff members per week with a monthly aggregate of 40 to validate the new process regarding EVS not cleaning a room until all specimens are removed is in place. The findings are reported monthly to the Transfusion Committee, Quality of Care Committee and quarterly to the Quality Committee of the Board of Trustees until 100% is sustained for 3 months.
- Ten (10) blood product release records from Transfusion Services are audited weekly with a monthly aggregate of 40 by Transfusions Services Leadership for documentation of training prior to release of the blood product and from point of issue to start time of the blood. The findings are reported monthly to the Transfusion Committee, Quality of Care Committee, Medical Executive Committee and quarterly to the

Transfusion Committee, Quality of Care Committee, Medical Executive Committee and quarterly to the Quality Committee of the Board of Trustees until 100% is sustained for 3 months.	All reported possible blood transfusion reactions are reviewed and analyzed by a Pathologist daily. Results are aggregated monthly by the Transfusion Services and reported to the Transfusion Committee. The findings are reported monthly to the Transfusion Committee, Quality of Care	Committee and quarterly to the Quality Committee of the Board of Trustees.	Individual deficiencies will be reported to the appropriate supervisor or manager. Any deficiencies will be addressed with the individual through training, re-education and/or following the human resources corrective action process.	When 100% compliance is sustained for 3 months the monitoring will continue on an ongoing basis quarterly. If compliance is not sustained quarterly monitoring will go back to weekly with data aggregated monthly for sustained compliance for at least 3 consecutive months. Decisions will be made in accordance with national clinical standards and regulations.
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